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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/597,532      | 07/28/2006  | Matthew Bruce        | US040117US          | 4274             |

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| EXAMINER |
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NGUYEN, HIEN NGOC

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| ART UNIT | PAPER NUMBER |
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3768

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03/30/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/597,532 | <b>Applicant(s)</b><br>BRUCE ET AL. |  |
|                              | <b>Examiner</b><br>HIEN NGUYEN       | <b>Art Unit</b><br>3768             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/28/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 1-10, drawn to a method of ultrasonically imaging blood perfusion and blood flow in a region of interest.

Group 2, claims 11-20, drawn to an ultrasonic diagnostic imaging system for imaging both perfusion and flow in a body infused with a contrast agent.

The inventions listed as Groups 1 and 2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common special technical feature for both groups is the infusing contrast agent. This element cannot be a special technical feature under PCT rule 13.2 because the element is shown in the prior art. US Patent 7,374,744 discloses infusing contrast agent into the body to enhance imaging (see col. 2, lines 54-67).

During a telephone conversation with Mr. W. Brinton Yorks on 03/18/09 a provisional election was made without traverse to prosecute the invention of Group 1,

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claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

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§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Brock-Fisher et al. (US 2003/0204142).

Regarding claim 1-7 and 9 Brock-Fisher discloses a method of ultrasonically imaging blood perfusion and blood flow comprising:

- acquiring a sequence of ultrasonic echo signals from a body which has been infused with an ultrasonic contrast agent; (see abstract and [0011-0014]).
- processing the echo signals to detect the tissue structure in the absence of microbubbles; (see abstract and [0011-0014]).

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- processing a plurality of the echo signals in a first way to detect echo signals returned from tissue microvasculature perfuse with the contrast agent; (see [0011-0014] and [0037]). The first way is to detect amplitude of the return echo signal.
- processing a plurality of the echo signals in a second way to detect echoes returned from blood flow containing the contrast agent in larger vessels; (see [0011-0014], [0075] and [0078]). The second way is to detect echo signal using Doppler mode.
- utilizing the echo signals processed the first way to form a portion of an image depicting perfusion; (see [0037] and [0030-0039]).
- utilizing the echo signals processed the second way to form a portion of an image depicting blood flow in larger vessels; (see [0030-0039], [0075] and [0078]).
- displaying an ultrasound image depicting both contrast-enhanced perfusion and contrast-enhanced blood flow; (see [0011-0014] and [0030-0039]).
- depicting both the presence and locations of microbubbles in tissue and the velocity of microbubbles in blood flow; (see [0012]). The detected ultrasound echo signals provide the locations and velocity of microbubbles in the blood. From these echo signals operator display the location and velocity of the microbubbles in the blood.

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- deciding the portion of the image which an echo signal is to form on the basis of a blood flow velocity estimation; (see [0003-0005] and [0011-0014]).
- deciding the portion of the image which an echo signal is to form on the basis of a blood flow variance estimation; (see [0011-0014], [0075] and [0078]). Image is formed from the detect echo signals. These signals are detected using Doppler mode. Doppler mode determines the blood flow variance estimation from the echo signals and form an image base on this variance estimation.
- processing a plurality of echo signals in first and second ways comprises processing the same ensemble of echo signals in first and second ways; (see abstract, [0011-0014], [0037], [0075] and [0078]). The system with multiple processors process the echo signals for amplitude and using Doppler mode.
- acquiring an ensemble of echoes over time from each of a plurality of different locations in the body; (see abstract, Fig. 9 and [0011-0014]). Contrast is introduced into the body and it flow to many locations in the body over time. It is clear that Brock-Fisher acquire an ensemble of echoes over time in many locations in the body as he images the contrast agent diffuse throughout the body.
- utilizing the echo signals processed the first way further comprises forming a perfusion image; utilizing the echo signals processed the second way

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further comprises forming a flow image; displaying an ultrasound image further comprises displaying the perfusion image overlaid with the flow image; (see [0003-0005], [0011-0014], [0030-0039], [0075] and [0078]).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brock-Fisher et al. (US 2003/0204142) in view of Burns et al. (US 6,095,980).

Brock-Fisher discloses substantially all claim limitations set forth in claim

7. However, he does not detecting nonlinear components of the echo signals by the pulse inversion technique. Burns discloses:

- detecting nonlinear components of the echo signals by the pulse inversion technique to be more effective in separating overlap fundamental and harmonic energy; (see col. 1, lines 5-23 and 55-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Brock-Fisher's method to detect nonlinear components of the echo signals by the pulse inversion technique as taught by Burns because this technique is more effective in separating overlap fundamental and harmonic energy and produce a higher quality image.



5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brock-Fisher et al. (US 2003/0204142), in view of Burns et al. (US 6,095,980) and further in view of Bruce et al. (US 6,620,103).

Brock-Fisher discloses substantially all claim limitations set forth in claim 1. He also discloses transmitting a plurality of differently modulated transmit pulses (see [0012]). However, he does not disclose transmitting differently modulated pulses in each of a plurality of different beam directions and detecting harmonic components of the echo signals by the pulse inversion technique.

Bruce discloses:

- transmitting differently modulated pulses in each of a plurality of different beam directions to acquire echoes which can be combined to separate harmonic frequencies by pulse inversion; (see abstract, claims 19 and 23).

Burns discloses:

- detecting nonlinear components of the echo signals by the pulse inversion technique to be more effective in separating overlap fundamental and harmonic energy; (see col. 1, lines 5-23 and 55-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Brock-Fisher's method to transmit differently modulated pulses in each of a plurality of different beam directions and detect nonlinear components of the echo signals by the pulse inversion technique as taught by Bruce and Burns in order to acquire echoes which can be combined to separate

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harmonic frequencies by pulse inversion; pulse inversion technique is more effective in separating overlap fundamental and harmonic energy and produce a higher quality image.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HIEN NGUYEN whose telephone number is (571)270-7031. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./  
Examiner, Art Unit 3768

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768